510(k) SUMMARY-Revised

JUL 15 2013

DenTek Oral Care Inc.'s
Easy Brush with fluoride (**K130186**)

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Linda Giles
Date Prepared: January 24, 2013
Revision Date: June 12, 2013

Name of Device and Name/Address of Sponsor

Easy Brush with fluoride
DenTek Oral Care, Inc.
307 Excellence Way
Maryville, TN 37801
Phone: (865) 983-1300
Facsimile: (865) 983-2444

Common or Usual Name

Interdental brush

Classification Name

Manual toothbrush

Classification Product Code

EFW, Class I

Predicate Devices

Oral-B Woodsticks with Fluoride (K942633) and "Johnson & Johnson Fluoride Dental Floss, Mint Waxed" (K935440).

Purpose of the Traditional 510(k) notice.

The Easy Brush with fluoride is a modification to DenTek Oral Care Inc.'s Easy Brush, FDA device listing number B094614, on which a flavor and fluoride solution has been applied. Each brush contains approximately 0.15mg sodium fluoride in the flavor coating.

Intended Use

The Easy Brush with fluoride is intended to mechanically remove plaque and food particles from between teeth to reduce tooth decay. It is to be used with an in and out motion to clean between interdental space as it is done with floss, and other interdental cleaners such as tooth picks.

Technological Characteristics

The Easy Brush with fluoride is an interdental brush designed to clean between teeth. It is composed of 4 parts (a handle, a wire, bristles, and a cap). The wire is twisted around the nylon filaments to create the brush, and then is molded onto a plastic handle. It is then coated with a solution containing flavor and sodium fluoride and then capped off.

Substantial Equivalence

The Easy Brush with fluoride is intended to mechanically remove plaque and food particles from between teeth to reduce tooth decay. As described in more detail in the Substantial Equivalence Chart-Revised, (page 4 of this submission), which lists the devices' similarities and differences, the Easy Brush with fluoride has the same intended use as "Oral-B Interdental Woodsticks with Fluoride" (K942633) and "Johnson & Johnson Fluoride Dental Floss, Mint Waxed" (K935440).

Biocompatibility

The biocompatibility of the device relies upon testing done on approved devices such as DENTSPLY 5% Sodium Fluoride Varnish K122331, which was reported to have no biocompatibility issues, and upon the predicate devices mentioned above which contain an amount of sodium fluoride that is substantially equivalent to the subject Easy Brush with fluoride. In addition, bottled drinking water and tap water are also approved to contain sodium fluoride in amounts proven to be safe and beneficial to the public as an anti-caries agent. Therefore, the Easy Brush with fluoride at a level of approximately 0.15 mg per brush is also biocompatible.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 15, 2013

DenTek Oral Care, Incorporated
Ms. Linda Giles
Regulatory Specialist
307 Excellence Way
MARYVILLE TN 37801

Re: K130186
Trade/Device Name: Easy Brush with Fluoride
Regulation Number: 21 CFR 872.6855
Regulation Name: Manual Toothbrush
Regulatory Class: I
Product Code: EFW
Dated: June 12, 2013
Received: June 13, 2013

Dear Ms. Giles:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K130186

Device Name: Easy Brush with fluoride

Indications for Use:

The Easy Brush with fluoride is intended to mechanically remove plaque and food particles from between teeth to reduce tooth decay. It is to be used with an in and out motion to clean interdental spaces, as it is done with dental floss.

Prescription Use _____ AND/OR Over-The-Counter Use_X_
(Per 21 C.F.R. 801.109) (Per 21 C.F.R. 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S. Runner -S
Susan Runner DDS MA 2013.07.12
14:13:46 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K130186